Agenda

I. PMRA status re: Seresto (any new info), including status causality analysis

II. Upcoming meetings/presentations

A. Bayer Seresto Meeting

Ex. 5 Deliberative Process (DP)

B. Spot-on Webinar
- early history/2008-9 special review
- look at post special review submissions – inconsistencies
- determination to require template
- plans for template/how to use – including some examples (tree diagram?)
- going through template
- questions/next steps

C. AHI meeting
- Generic, follow on from spot-on webinar. Perhaps more details on analysis plans
- Include some discussion (short) on upcoming AHI-sponsored PV training in October.

III. Recap of Rick Kingston meeting (see notes below)

5/18/16

Notes from the 5/13/16 HED Touch Base with Rick Kingston

- *[Discuss the PSP*

-Kingston noted that the FY 2015 PSP report should be received by July 2016. Final cumulative report with "advanced" analysis should be received later in 2016.
-The Pyrethrin Stewardship Program expert panel will be reconvening later this year- select OPP staff are invited to attend]

- Spot on data collection
    - OPP finalized the spot-on template after having a meeting with FDA's CVM a few weeks back and received comments on the template last week.
    - Template to go out to registrants next week –

Liz checked status with Anne Overstreet on 5/18/16 – the OPP Update is not out until sometime next week

    - June 7th Webinar with Spot-On registrants to review the template
    - We will ask for 9 registrants to volunteer to pilot this for a year and plan to make adjustments along the way.

Kingston's comments on the current draft of the Spot-On template:

- Kingston most companies do not have pharmacovigilance or health care specialists on staff
    - VICH will be too much for most companies *[note: FDA CVM strongly recommended VICH]*
    - Consider delaying pilot and allowing companies to take a look at their data system
    - Doesn't think companies will be able to easily use spreadsheet unless they have PV Works

-variables he does not think registrants can answer the orange highlighted parts in the template- including (not limited to) Row 9 – Duration of product use; row 21- Concomitant Products; Row 31- Approximate age marker; Rows 38-41/Routes of exposure- we should revert back to the ~6 basic routes of exposure

-EPA needs to keep in mind that nearly all of the affected registrants are clueless regarding VedDra and terminology. The staff talking calls are not necessarily highly trained. When we remarked that during a meeting with AHI that all seemed to understand the value of a consistent vocabulary and generally agreed with these efforts, Rick indicated that those are higher level folks with less "front line" experience. So he predicts problems. DavidJ said that it may simply be that EPA has "upped the game" and that it will ultimately be the risk managers in RD that will need to decide in how much is too much to expect.

-Row 41/Symptoms: Symptom ~ Onset ~ Duration – loosely based upon HED review of Seresto incident data and trouble with the lumping of symptoms – data analysis implications

-Kingston noted that Bayer is very sophisticated, Seresto et. al reporting from Bayer represents the highest level of sophistication for animal incident data – consider not separating out each symptom but recording the onset of the "constellation of symptoms"

-Combine Rows 42 and 43- management site- where? At home or not?

-Aggregate the minor severity cases which will be the vast majority of cases to code and take up the most time and effort. Have only a few variables for the minor case coding- will considerably ease registrant load and allow them to focus on the more important moderate, major, and deaths. Perhaps have separate spreadsheets – a shorter one for minors (e.g, maybe 6 entries) and the longer one for others. *[Note: may need to better define how these are classified]*

Other notes:

-EPA should clarify the focus on moderate and major severity and fatal cases

-Two templates: 1. Wishlist for death/high/moderate cases 2. Barebones list (counts/symptoms)

-Moving to the template will be a "huge paradigm shift for the entire market"

-Simplify the template to: not scare away volunteers but attract them

-Encouraging standardization is a step in the right direction because it "levels the playing field"

-Consider asking the registrants for a critical analysis of the death, major moderate data and aggregate report for minors.

-Most companies collecting Spot-On data are not set up for animals

-Kingston says that the spot-on template has huge implications across the board because the registrants can't change their reporting fields/systems easily

-The 2-year condition registration and ongoing requirements are a registrant concern that may be a factor affecting the template progress

-Minnesota Pet Port helpline is the industry standard??

- Kingston requested discussion the overall approach EPA is using to address Voluntary AE reporting (Rich Dumas' group)
- Streamlining of submissions for 6a2 including electronic methods of submitting, and of course the spot on data collection. I've been getting lots of feedback from registrants. Rich came to the CSPA Pest Management division meeting to discuss their program and it stimulated quite a bit of interest.
    - Registrant concerns abound

<u>To Dos:</u>

-David Miller to send Kingston the OIG report that critiques NTSA

-Kingston shared a New Yorker article

-Liz to email Kingston the new CRM for PSP- done!

-HED have a look at the report Safety Call produced for the Sargeant's Spot On enhanced reporting results- provide some informal feedback to Kingston

-Look at the causality scoring in this report and consider for expansion

- maybe this is a good way to do this - more objective? Score things o to 6 to achieve "unlikely" (0-2); "Possible (3-4); ;"Event of Interest" (5-6)

-HED catch RD and vets up to speed